

JUN 11 2007

ATTACHMENT 6-1



510(K) SUMMARY

**Given® Diagnostic System with
PillCam™ ESO2 Capsule**

510(k) Number K_____

Applicant's Name:

Given Imaging Ltd.
Hermon Building (Shaar Yoqneam)
New Industrial Zone
P.O. Box 258
Yoqneam 20692, Israel
Tel.: 011-972-4-9097730
Fax: 011-972-4-9592466

Contact Person:

Shosh Friedman, RAC
Senior Consultant
Tel: (403) 208-4916
Fax: (403) 208-4953
Email: Shosh.Friedman@givenimaging.com

Trade Name:

Given® Diagnostic System

Classification Name:

Ingestible Telemetric Esophageal Capsule Imaging System

Classification:

FDA has classified Ingestible Telemetric Esophageal Capsule Imaging System as class II devices (product code 78NSI, regulation number 21 CFR 876.1300) and they are reviewed by the Gastroenterology Panel.

Predicate Device:

Given® Diagnostic System with PillCam™ ESO Capsule cleared for marketing under K041149 and K042960

Performance Standards and Special Controls:

The Given® Diagnostic System complies with the requirements presented in "Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA" issued on November 28, 2001

Intended Use:

The Given® Diagnostic System with the PillCam™ ESO2 Capsule is intended for visualization of the esophageal mucosa.

Device Description:

The Given® Diagnostic System is comprised of three subsystems: PillCam™ Capsule (SB, ESO), Data Recorder Set, and RAPID® Workstation or RAPID® Software.

The modifications to the Given® Diagnostic System, which are subject of this Special 510(k) is the addition of a new model of esophageal capsule, the PillCam™ ESO2 Capsule, and the addition of an alternative ingestion procedure, the simplified ingestion procedure (SIP) for the esophageal capsules.

Substantial Equivalence:

Given Imaging Ltd. believes that the modified Given® Diagnostic System with the PillCam™ ESO Capsule is substantially equivalent to the market-cleared Given® Diagnostic System with the PillCam™ ESO2 Capsule without raising any new safety and/or efficacy issue.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Shoshana Friedman, RAC
Senior Consultant
Given® Imaging Ltd.
91 Rockyspring Cir. NW
Calgary, Alberta T3G 6A1
CANADA

JUN 11 2007

Re: K071153

Trade/Device Name: Given® Diagnostic System with PillCam™ ESO2 Capsule
Regulation Number: 21 CFR §876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NSI
Dated: May 30, 2007
Received: June 4, 2007

Dear Ms. Friedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

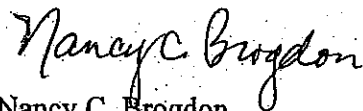
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|-----------------|----------------------------------|--------------|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 6-3

INDICATIONS FOR USE STATEMENT

510(k) Number: K071153

Device Name:

Given® Diagnostic System (with PillCam™ ESO2 Capsule)

Indications for Use:

The Given® Diagnostic System with the PillCam™ ESO2 Capsule is intended for visualization of the esophageal mucosa

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number K071153

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over the Counter Use _____



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K071153